Remarks/Arguments:

Introduction

Claims 1-32 are pending.

Section 102 Rejections

Claim 32 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,258,042 to Mehta. Applicants respectfully traverse.

Mehta is directed to a stent made from a polymeric hydrogel, such as a poly(vinyl)alcohol. (Mehta, column 5, lines 8-15). The stent is hydrated *in situ* to expand the stent to fit against a vessel wall. The stent has dehydrated outer diameters from between 1 and 3 mm. (Mehta, column 6, lines 15-16). Upon hydration, the stent expands by a factor of 1:2 to 1:4 in diameter. The increase in expanded or hydrated diameter occurs as hydrogel absorbs water and correspondingly increases the wall thickness of the hydrated stent. While the dehydrated stent may have a thin wall thickness of 25 to 100 microns, the implanted wall thickness is millimeter-sized and not micron sized.

In contrast, the present invention as currently define in claim 32 is directed to an implantable device. The implantable device comprises a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns and having opposed open ends to define a fluid passageway therebetween.

Mehta fails to disclose that its dehydrated stent is self-supporting. Mehta merely states that the stent may be placed on a balloon catheter for percutaneous delivery to an artery or vein. (Mehta, column 7, lines 43-45). Moreover, Mehta fails to disclose that the hydrated stent is

self-supporting. Mehta merely describes that once expanded, the stent is held in place in the vascular structure by tension. (Mehta, column 7, lines 54-57).

Because Mehta fails to disclose that its stent is self-supporting and fails to disclose the wall thickness of the implanted stent, i.e., the hydrated wall thickness, Mehta fails to disclose each and every element of the present invention as presently defined by claim 32. Therefore, reconsideration and withdrawal of the rejection of claim 32 is respectfully requested.

Section 103 Rejections

Claims 1-32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,290,720 to Khosravi et al. ("Khosravi") in view of U.S. Patent No. 5,922,339 to Usala ("Usala"). Applicants respectfully traverse.

Review Of Cited References:

Khosravi is directed to a stent-graft. (Khosravi, column 1, line 64). The graft is a tubular graft of "polyester, polytetrafluorethaline [sic], dacron, teflon or polyurethane". (Khosravi, column 2, lines 42-43). The stent is attached to the graft by sutures, staples, wires, adhesive bonding, thermal bonding, chemical bonding or ultrasonic bonding. (Khosravi, column 2, lines 43-46).

Khosravi, however, fails to teach or suggest a graft made from or comprising poly-para-xylylene. Moreover, Khosravi fails to teach any physical properties of its tubular graft, such as wall thickness.

Usala teaches that certain polymer coatings are useful against immune response for artificial organs and other transplants of both living and nonliving tissue. (Usala, column 2, lines 27-34). The coatings could be applied to stents, grafts, catheters or shunts. (Usala,

column 5, lines 61-64). The coatings are generally very thin at 100 to 200 Angstroms (0.01 to 0.02 microns), but could be as thick as 2,000 Angstroms (0.2 microns). (Usala, column 5, lines 34-35, lines 54-55). Usala further discloses membranes with a maximum thickness of about 7,500 Angstroms (0.75 microns). Usala discloses that such coatings could be used on stent or grafts, but Usala fails to teach or suggest that the stent or graft itself could be made from such polymers. (Usala, column 5, lines 58-64).

Thus, Usala is directed to very thin coatings or membranes having a thickness in the Angstrom range, i.e., less than a micron in wall thickness.

Moreover, upon further review of Usala, the polymers of Usala have backbones of only certain diphenyl alkenes or certain naphthalene derivatives. (Usala, column 3, lines 1-55). Usala contrasts these polymers from poly-para-xylylenes. (Usala, column 10, line 60, to column 11, line 35 (claims 1 and 2)). Further, **Usala expressly excludes poly-para-xylylenes** from its disclosed encapsulating polymeric materials, as follows:

> **[T]he present genus of encapsulating polymeric materials excludes poly-para-xylylene, poly-monochloro-xylylene and poly-dichloro-xylylene").** (Usala, column 4, lines 3-5) (emphasis added)

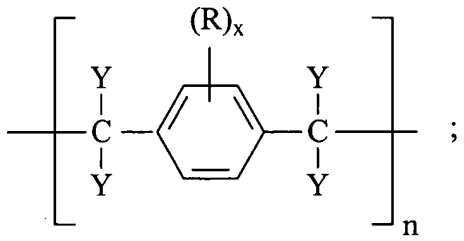
Thus, Usala expressly teaches away from the use of poly-para-xylylene as a polymeric material for use as a coating material.

For the reasons discussed below, claims 1-32 are patentably distinct over Khosravi and Usala.

Patentability of Independent Claims 1, 11, 16 and 27:

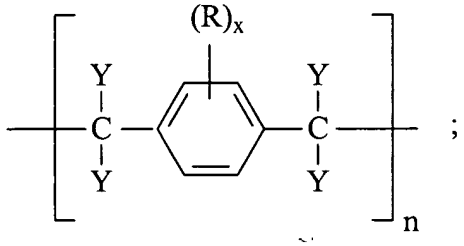
In contrast to Khosravi and Usala, the present invention as presently defined in Claim 1 is directed to a stent-graft endoprosthesis comprising (i) a seamless tubular graft of biocompatible polymeric material having a wall thickness defining a luminal surface and an

exterior surface; (ii) a radially expandable coated stent securably, circumferentially and axially disposed over said exterior surface, wherein said coated stent is coated with said biocompatible polymeric material; wherein said biocompatible polymeric material consists essentially of poly-para-xylylene having a formula of



wherein n is from about 10 to about 10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine.

In further contrast to Khosravi and Usala, the present invention as presently defined in Claim 11 is directed to a stent-graft endoprosthesis comprising (i) a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness defining a luminal surface and an exterior surface; and (ii) a radially expandable stent securably disposed over a portion of said exterior surface; wherein said polymeric material consists essentially of a poly-para-xylylene having a formula of



wherein n is from about 10 to about 10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy,

hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y , which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine.

In yet further contrast to Khosravi and Usala, the present invention as presently defined in Claim 16 is directed to a method for producing a stent-graft endoprosthesis comprising the steps of (i) providing a mandrel having a cylindrical outer surface; (ii) depositing a poly-para-xylylene polymer onto a portion of said outer surface of said mandrel to form a tubular polymeric graft having a wall thickness defining a luminal surface and an exterior surface of said graft; (iii) providing a radially expandable stent; and (iv) securing portions of said stent to portions of said outer surface of said graft to form said stent-graft endoprosthesis.

In still further contrast to Khosravi and Usala, the present invention as presently defined in Claim 27 is directed to a method for producing a stent-graft endoprosthesis comprising the steps of (i) providing a tubular graft of vacuum vapor deposited poly-para-xylylene polymer; (ii) providing a radially expandable stent; and (iii) securing portions of said stent to portions of said outer surface of said graft to form said stent-graft endoprosthesis.

Applicants respectfully submit that Khosravi and Usala, alone or in combination, fail to teach or suggest a tubular graft made of poly-para-xylylene as set forth in independent claims 1 and 11. As described above, Khosravi fails to teach or suggest a graft made of poly-para-xylylene. Usala merely teaches that a graft or a stent may be coated with a very thin, Angstrom-sized polymeric coating of certain diphenyl and naphthalene derivatives. Usala excludes the use poly-para-xylylenes as polymeric coatings. Thus, Usala teaches away from the present invention as presently defined in independent Claims 1, 11, 16 and 27, which include poly-para-xylylenes.

Even assuming *arguendo* that the coating of Usala may be poly-para-xylylene, Usala still fails to teach or suggest that a graft itself could be made of poly-para-xylylene. Usala fails

to disclose the material of construction of the underlying graft. The coating of Usala is applied to change the property of the underlying graft, such as tissue or cell adherence of the underlying graft. (Usala, column 5, lines 54-64). Thus, Usala teaches that the coating and the underlying graft must be of different materials. Accordingly, Usala fails to teach or suggest a graft made of a single polymeric material, such as poly-para-xylylene.

Therefore, the combination of Khosravi and Usala fail to teach the present invention because neither teach nor suggest a polymeric graft made of poly-para-xylylene. Thus, because of the deficiencies in the Khosravi and Usala references the only way to arrive at the present invention from such a combination of references is through hindsight reconstruction using Applicants' own Specification as a roadmap. Such hindsight reconstruction, however, is impermissible and fails to present a *prima facie* case of obviousness. Moreover, such hindsight reconstruction is contrary to the specific teachings of Usala.

Thus, the stent-graft endoprostheses of claims 1 and 11 are patentably distinct over Khosravi and Usala. Further these references also fail to teach or suggest the methods for producing stent-graft endoprostheses according to claims 16 and 27 of the present application.

Therefore, reconsideration and withdrawal of the rejections of claims 1, 11, 16 and 27, and all claims dependent therefrom, under 35 U.S.C. § 103(a) are respectfully requested.

Patentability of Independent Claims 3, and 32:

In contrast to Khosravi and Usala, the present invention as presently defined in Claim 3 is directed to an implantable stent-graft device comprising (i) a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns defining a luminal surface and an exterior surface; and (ii) a

radially expandable stent securably disposed over a portion of said exterior surface. (emphasis added).

In further contrast to Khosravi and Usala, the present invention as presently defined in Claim 32 is directed to an implantable graft device comprising (i) a seamless and self supporting tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 100 microns and having opposed open ends to define a fluid passageway therebetween. (emphasis added).

Khosravi and Usala, alone or in combination, fail to teach or suggest the present invention of claims 3 and 32. Except for a graft being made from polymeric material, Khosravi fails to teach or suggest any additional physical properties of its graft, including wall thickness of its graft. Usala fails to teach or suggest a stent-graft having graft with a wall thickness from about 10 to about 100 microns or a self-supporting graft having a graft wall thickness from about 10 to about 250 microns. Usala is directed to very thin coatings or membranes that are Angstrom-sized in thickness. Thus, the combination of Khosravi and Usala fail to teach or suggest the present invention as set forth in claims 3 and 32 because the combination fails to teach or suggest a graft having a wall thickness of about 10 microns to about 100 microns or a self-supporting tubular graft having a wall thickness from about 10 microns to about 250 microns.

Further, Applicants respectfully disagree with the Examiner's that the "range of the wall thickness of the graft as claims is known in the art". (Office Action, page 3). As noted in paragraph [0049] of the Specification, prior art grafts have minimum wall thicknesses in the millimeter range (as contrasted to the micron-sized range), with the exception of expanded polytetrafluoroethylene grafts which may have a minimum wall thickness of about 200 microns. As described in paragraph [0049], however, such thin-walled expanded polytetrafluoroethylene grafts are not self-supporting.

The Examiner cites U.S. Patent Nos. 5,258,042 to Mehta and 5,464,450 to Buscemi et al ("Buscemi") to support the allegation that the claimed micron-sized, thin walled grafts of the present invention were well known in the art. Contrary to the Examiner's assertion, Buscemi does not support such an allegation.

As discussed above, Mehta fails to disclose that a micron-sized, dehydrated stent may be self-supporting. Further, such a micron-sized, dehydrated stent must undergo considerable expansion to be of any use as an implantable device. Moreover, the wall thickness of the implanted stent, i.e., the hydrated wall thickness, is not specifically disclosed, but is likely to be millimeter-sized as Mehta describes that the dehydrated stent must be hydrated to expand against a vessel wall.

Thus, Mehta fails to support the Examiner's assertion that micron-sized, self-supporting grafts were well known at the time of the present invention.

Buscemi is directed to a biodegradable stent 10. (Buscemi, column 3, lines 7-8). The stent 10 includes a main tubular body 11 and a plurality of fibers 18 wrapped around the main tubular body 11. (Buscemi, column 3, lines 16-18). The wall thickness of the main tubular body is described as being about 0.25 millimeters. (Buscemi, column 4, lines 26-27). The diameter of the fibers is described as being about 0.2 millimeters in diameter. (Buscemi, column 3, lines 60-62, and column 6, lines 41-42). Thus, the stent of Buscemi has a wall thickness of about 0.45 millimeters.

Buscemi does mention that the fibers 18 may be hollow fibers. (Buscemi, column 3, lines 62-64). These hollow fibers may have a wall thickness from 25 to 100 microns. (Id.). As is apparent from the discussion above, such a teaching of the wall thickness of individual fibers *per se*, however, is not a teaching of the overall wall thickness of the stent itself.

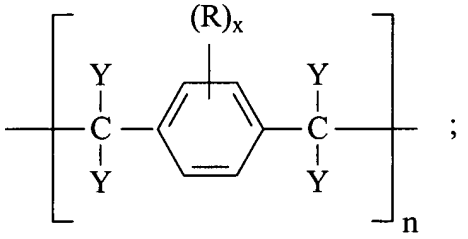
Thus, Buscemi also fails to support the Examiner's assertion that micron-sized, self-supporting grafts were well known at the time of the present invention.

Thus, despite the Examiner's assertion that the claimed wall thicknesses are allegedly known in the art, Applicants respectfully submit that the recitations of self-supporting and the wall thicknesses of claims 3 and 32 are not taught nor suggested by the prior art.

Therefore, reconsideration and withdrawal of the rejections of claims 3 and 32, and all claims dependent therefrom, under 35 U.S.C. § 103(a) are respectfully requested.

Patentability of Independent Claims 8 and 29:

In contrast to Khosravi and Usala, the present invention as presently defined in Claim 8 is directed to a stent-graft endoprosthesis comprising (i) a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 250 microns defining a luminal surface and an exterior surface; and (ii) a radially expandable stent securably disposed over portion of said exterior surface; wherein said polymeric material comprises a poly-para-xylylene having a formula of



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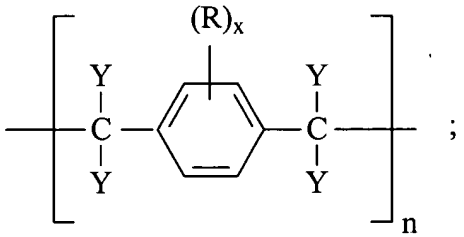
wherein n is from about 10 to about 10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine. (emphasis added).

In further contrast to Khosravi and Usala, the present invention as presently defined in Claim 29 is directed to an endoprosthesis comprising (i) a seamless tubular non-textile graft of biocompatible polymeric material having a wall thickness of about 10 microns to about 250 microns defining a luminal surface and an exterior surface; wherein said polymeric material is a poly-para-xylylene having a formula of



wherein n is from about 10 to about 10,000, x is from 0 to 4, R, which can be the same or different, is alkyl, aryl, alkenyl, amino, cyano, carboxyl, alkoxy, hydroxylalkyl, carbalkoxy, hydroxyl, nitro, chlorine, bromine, iodine and fluorine, and Y, which can be the same or different, is hydrogen, chlorine, bromine, iodine and fluorine. (emphasis added).

Khosravi and Usala, alone or in combination, fail to teach or suggest the present invention of claims 8 and 29. As discussed above, Khosravi and Usala fail to teach or suggest a graft being made from poly-para-xylylene and fail to teach or suggest a graft with a wall thickness from about 10 to about 250 microns.

Thus, the combination of Khosravi and Usala fail to teach or suggest the present invention as set forth in claims 8 and 29 because the combination fails to teach or suggest a tubular poly-para-xylylene graft having a wall thickness from about 10 microns to about 250 microns.

Therefore, reconsideration and withdrawal of the rejections of claims 8 and 29, and all claims dependent therefrom, under 35 U.S.C. § 103(a) are respectfully requested.

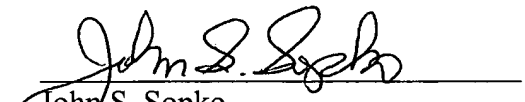
Summary

Therefore, Applicants respectfully submit that independent claims 1, 3, 8, 11, 16, 27, 29 and 32, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,



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